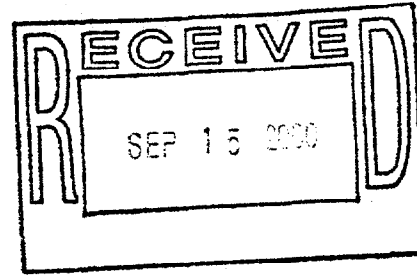


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August 30, 2000



The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra Wisconsin 53156-0904, is making the following statements:

- (1) Cyro-Yeast combines a portion of the nutritional ingredients found in Catalyn® with a lactic acid yeast base to promote digestive cleansing and nutritional building.
- (2) The natural, whole food ingredients found in Cyro-Yeast work together to perform both cleansing and building functions simultaneously. Consistent cleansing of the gastrointestinal tract along with nutritional support promotes overall health and returns balance to our all too often unbalanced diet.
- (3) Cyro-Yeast maintains a healthy digestive system.
- (4) Carrot, soy, and alfalfa help lubricate intestines and stimulate waste elimination. Rice bran helps stimulate bowel movement. Carrot helps balance stomach acid and encourages proper assimilation of nutrients. Vitamin B1 (thiamine) helps produce hydrochloric acid needed for proper digestion. Vitamins A and B2 (riboflavin) work together to help keep mucous membranes in the gastrointestinal tract healthy. Carrot contains fiber to influence bowel motility. Alfalfa works to cleanse and tone the intestinal tract. Chlorophyll found in alfalfa encourages the growth and proliferation of healthy intestinal flora. The intestines require vitamin D, also found in alfalfa, to absorb and use calcium and phosphorus.
- (5) Cyro-Yeast promotes nutritional balance.
- (6) Unlike live yeast that robs the body of precious B-complex vitamins and other nutrients, the live cells in nutritional yeast are destroyed, leaving the nutrients available for assimilation.

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Whole Food Supplements

- (7) Beta-carotene helps protect cells from damage caused by free radicals while silicon assists in calcium absorption and helps build strong connective tissue.
- (8) Cyro-Yeast includes most of the ingredients in Catalyn®, our multivitamin, a whole food source of vitamin, mineral, and glandular complexes with their associated trace minerals, enzymes, and proteins to cover a broad spectrum of nutritional factors.
- (9) The nutritional yeast, in lactic acid yeast, encourages the growth and proliferation of healthy intestinal flora by supporting proper pH balance, vital for the promotion of nutrient absorption, beneficial for the overall healthy functioning of the gastrointestinal system.
- (10) Multiple glandular ingredients from a variety of animal sources to provide nutrients and support for the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of nutritional yeast, whey, malt syrup, defatted wheat (germ), carrot (root), bovine liver, bovine adrenal, bovine kidney, bovine spleen, ovine spleen, dried alfalfa juice, rice (bran), mushroom, soy bean leithin, and ascorbic acid. Other ingredients include honey, arabic gum, calcium stearate, vitamin A palmitate, pyridoxine hydrochloride, cocarboxylase, riboflavin, and cholecalciferol. The name of the product is Cyro-Yeast®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

